

applicant's admissions. Claims 29-31 are also rejected under 35 U.S.C. 103 as being unpatentable for obviousness.

The Examiner also rejected as evidence Dr. Kreamer's signed declaration dated January 22, 2003 as "hearsay" and inadmissible. Applicant objects to this statement on two grounds. First, administrative agencies such as the PTO are not bound by the rules of evidence that govern judicial proceedings. *See* Federal Rules of Evidence 1101. While administrative agencies may provide for application of these rules, and the PTO has adopted these rules in the case of patent interference proceedings and patent public use proceedings, it has not adopted the Federal Rules of Evidence for *ex parte* examinations. *In re Epstein*, 32 F.3d 1559 (Fed. Cir. 1994).

Secondly, the Applicant objects to the rejection because the declaration does not amount to hearsay, and complies with the requirements for declarations as set out in 37 C.F.R. Section 1.131. A statement of facts in an affidavit must "... be such, in character and weight, as to establish ... conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application." 37 C.F.R. 1.131(2)(b). Dr. Kreamer's declaration establishes that it was he who conceived of the invention, and filed an initial application filed March 1, 1989. The University of Southern California study was published November 18, 1989. The inventor's earlier application therefore predates this reference the Examiner is using as prior art. Regardless, this USC study did not contemplate the invention; it only contemplated the effect of aspirin, not of an aspirin-vitamin combination. These facts, set out in the declaration, should be accepted as evidence under Section 1.131.

The Examiner states in his response to Applicant's remarks of January 28, 2003 that there is a discrepancy as to whether the University of Southern California's study was published or unpublished, and the appropriate dates. There are, in fact, two studies conducted by the University of Southern California, one that was published on November 18, 1989, and a second set of data compiled after Dr. Kreamer's suggestion.

As stated in the declaration filed January 28, 2003, subsection 2, the University of California conducted an observational study first published November 18, 1989. This publication only included and analyzed the data referring to aspirin use. This published study did not analyze or consider the effects of aspirin combined with vitamin use.

A second data set was compiled by USC, at the Applicant's request referred to by the phone call described in paragraph 2 of the affidavit, which considered the combined use of vitamins and aspirin. This is the unpublished data referred to by paragraph 14 of Dr. Hollier's declaration.

The Examiner suggests that the only way the discrepancy between the two declarations can be resolved is through submission of a declaration by USC. Applicant respectfully disagrees, in that the discrepancy can be resolved simply by distinguishing between the published study, conducted by USC and published November 18, 1989; and the non-published data, compiled later after Dr. Kreamer's request.

Applicant is unsure how to interpret Examiner's statement in the following sentence from the final office action, "However, so a full individual examination and study can be made, has not received a copy of this publication." Applicant assumes this sentence refers to this confusion between the two studies, and the confusion is remedied by the above explanation.

In light of this clarification, the Applicant objects to the rejection of the application under 35 U.S.C. 102 (a) or (f). The initial patent application for the present invention was filed on March 1, 1989. While priority is not claimed to this application, it does establish a date of invention that precedes the November 18, 1989 publication date of the published USC study. Accordingly, the study is not prior art under 102(a) or (f), this notwithstanding the fact that the published USC study does not anticipate the invention, as the data on vitamins was not appreciated until the Applicant's request.

The applicant respectfully disagrees with Examiner's obviousness rejection under 35 U.S.C. §103. Obviousness can be overcome by a showing of unexpected or surprising results. As stated by the CCPA, "The fact that an invention provides results which would not have been expected by those skilled in the art is strong evidence in rebuttal of an assertion that the invention would have been obvious". *In re Klosak*, 455 F.2d 1077 (C.C.P.A. 1972). The application alleges the differences between the expected combination of vitamins and aspirin as they differ from either administration alone. The Examiner has cited no art that teaches the combination of vitamins and aspirin to produce this desired effect, and mere hindsight combination of references is not enough.

Based on the foregoing, Applicant respectfully submits that its claims are in condition for allowance at this time, patentably distinguished over the prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-2500 to discuss the claims in an effort to reach a mutual agreement with respect to claim

limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed adequate for this purpose.

Respectfully Submitted,

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Daniel A. Rosenberg
Daniel A. Rosenberg
Registration No. 44,308
DAVIS, BROWN, KOEHN,
SHORS & ROBERTS, P.C.
666 Walnut St., Suite 2500
Des Moines, Iowa 50309
Telephone: (515) 288-2500

ATTORNEYS FOR APPLICANT

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Assistant Commissioner for Trademarks, 2900
Crystal Drive, Arlington, Virginia 22202-3513, on

July 7, 2003
By: Lisa J. McKen